UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: Nexium (Esomeprazole Magnesium) Antitrust Litigation This Document Relates to: All Actions	MDL No. 2409 Civil Action No. 1:12-md-02409-WGY

MEMORANDUM IN SUPPORT OF TEVA DEFENDANTS' MOTION FOR SUMMARY JUDGMENT BASED ON ABSENCE OF REVERSE PAYMENT TO TEVA

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INTRODUCTION

When it comes to plaintiffs' claims against Teva, the emperor simply has no clothes. With fact and expert discovery now complete, it is clear that plaintiffs cannot meet their burden to prove the existence of any reverse payment from AstraZeneca to Teva, let alone a "large, unjustified reverse payment," as required for an actionable antitrust claim. Since that is the sole anti-competitive conduct alleged against Teva in the operative complaints, Teva is entitled to summary judgment on all counts.

In *Federal Trade Commission v. Actavis, Inc.* ("*Actavis*"), 133 S. Ct. 2223 (2013), the Supreme Court held that patent settlements involving reverse payments are subject to antitrust scrutiny under a rule of reason standard. But in that same ruling, the Supreme Court also held that litigants ***may*** settle patent infringement cases ***without any risk*** of antitrust liability when the settlement does not contain a "large, unjustified reverse payment" or involves "traditional settlement considerations." *Id*. at 2236-37. In so doing, the Court explicitly authorized: (i) settlements "allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger," and (ii) settlements compromising a damages claim for less than the amount of the defendant's exposure, holding that such "commonplace" settlements are not "subject to antitrust liability." *Id.* at 2233, 2237.

That is the situation presented here. It is undisputed that the settlement agreement resolving the Nexium (esomeprazole) patent litigation between AstraZeneca and Teva permits Teva to enter the market with generic Nexium by May 27, 2014 — well prior to the expiration of AstraZeneca's last Nexium patent. It is also undisputed that the Nexium settlement does not provide for a payment of any kind from AstraZeneca to Teva; plaintiffs do not even allege any payment from AstraZeneca to Teva in the Nexium settlement agreement.

Rather, plaintiffs claim that AstraZeneca made an implicit reverse payment to Teva by agreeing, at the same time it entered into the Nexium settlement, to a separate settlement agreement to resolve unrelated litigation involving AstraZeneca's patents for the drug Prilosec (omeprazole). In that case, AstraZeneca, again the branded manufacturer, sued Teva for patent infringement for Teva's at-risk launch of generic omeprazole. In the Prilosec settlement, Teva paid $9 million ***to*** AstraZeneca to resolve all infringement claims against Teva. Plaintiffs nonetheless allege this payment ***by*** Teva was an effective payment ***to*** Teva from AstraZeneca because Teva supposedly faced potential exposure well above $9 million. The undisputed facts, however, show there is no triable issue and Teva is entitled to summary judgment.

First, settlements providing for market entry before patent expiration without any payment from the patent holder to the generic, and settlements that reflect a compromise of a patent damages claim for less than the asserted value of that claim are sanctioned under *Actavis*, and therefore cannot form the basis for a legally viable antitrust claim. The *Actavis* Court expressly rejected the notion that a settlement at an amount that reflects a "discount" off the defendant's possible exposure constitutes an actionable "implicit net payment," and further held that parties do not "risk[] antitrust liability" if they enter into a settlement "allowing the generic manufacturer to enter the patentee's market, prior to expiration, without the patentee paying the challenger to stay out prior to that point." *Actavis*, 133 S. Ct. at 2233, 2237. The Nexium and Prilosec settlements here fall squarely within this safe harbor. (*See* Part I below.)

Second, given the Supreme Court has recognized that settling a damages claim at a 60% "discount" is not actionable, *id.* at 2233, for such a settlement to conceivably amount to a reverse payment, it would need to be so far outside the range of reasonableness as to be a sham — which plaintiffs here do not even allege much less present evidence to support. Given the strong public

policy favoring settlement, courts should not second-guess the reasonableness of business decisions to settle cases and the valuation of the same. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 200 (E.D.N.Y. 2003) ("*In re Cipro*"). (*See* Part II below.)

Third, even if plaintiffs were correct (and they are not) that the law permits antitrust scrutiny of the settlement of a damages claim to assess how the settlement amount compares to what the plaintiff might have stood to recover in the case, plaintiffs have no admissible evidence sufficient to prove that AstraZeneca reasonably stood to recover an amount so much greater than $9 million from Teva in the Prilosec litigation that it rendered the settlement unreasonable. Moreover, the conclusory opinions of their proposed "experts" fail to satisfy the requirements of *Daubert* and Fed. R. Evid. 702, as all three plaintiffs' experts ignore the legally-mandated *Georgia-Pacific* factors for estimating royalty damages. *See* Teva's Motion to Exclude Proposed Expert Testimony filed herewith. (*See* Part III below.)

Fourth, even if there were any triable issue as to the existence of a "reverse payment" to Teva, plaintiffs cannot prove that any such payment was "large" and "unexplained" as required by *Actavis*. That is, even accepting the inadmissible expert testimony proffered by plaintiffs that the Prilosec settlement reflects an effective $23 million "discount" to Teva, no reasonable jury could find this constitutes a "large" reverse payment intended to compensate Teva for "staying out" of the Nexium market until May 2014, given that plaintiffs themselves allege that Nexium sales exceed *$3 billion annually*. (*See* Part IV below.)

Plaintiffs survived Teva's motion to dismiss because the Court held that *Actavis* did not "explicitly require some sort of monetary transaction to take place for an agreement between a brand and generic manufacturer to constitute a reverse payment." Sept. 11, 2013 Opinion ("Op.") (ECF No. 352) 42. Thus, while the Court did not require a *monetary* transaction, it still

required a *payment*. Based on the undisputed facts, plaintiffs cannot prove that Teva received any "payment" here, let alone a "large unexplained" payment. Accordingly, Teva is entitled to summary judgment under *Celotex Corp. v. Catrett*, 477 U.S. 317, 325, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986).

BACKGROUND

A. Nexium Litigation

AstraZeneca holds a series of patents, the last of which expires in 2018/2019, related to Nexium. Teva Statement of Undisputed Facts ("SOUF") ¶ 2. Before its merger with Teva, Ivax filed an ANDA for generic Nexium on November 23, 2005. SOUF ¶ 3. In response to Teva's Paragraph IV notice, AstraZeneca sued Teva in March 2006. *Id.* After AstraZeneca settled its Nexium lawsuit with the first-ANDA filer, Ranbaxy, in April of 2008, Teva filed a declaratory judgment action seeking a ruling of invalidity and non-infringement regarding the Orange Book-listed patents not at issue in AstraZeneca's suit against Teva. SOUF ¶ 4.

In January 2010, AstraZeneca and Teva reached a settlement, and the district court entered a consent judgment resolving the Nexium patent litigation and permitting Teva to enter the market with generic Nexium by May 27, 2014, *more than four years* before the expiration of the asserted Nexium patents. SOUF ¶ 5.

B. Prilosec Litigation

Since 1989, AstraZeneca has sold omeprazole under the brand name Prilosec. SOUF ¶ 7. In December 2002, Schwarz-KUDCO began selling a generic version of omeprazole, after that product was found not to infringe AstraZeneca's patents. *Astra Aktiebolag v. Andrx Pharms. Inc.*, 222 F. Supp. 2d 423 (S.D.N.Y. 2002), *aff'd*, *In re Omeprazole Patent Litig.*, 84 F. App'x 76 (Fed. Cir. 2003); SOUF ¶ 9. Three additional generics, Mylan, Novartis (Lek), and Apotex, entered in 2003 — Mylan and Lek also prevailed on their non-infringement claims. *In re*

Omeprazole Patent Litig., 490 F. Supp. 2d 381 (S.D.N.Y. 2007); SOUF ¶ 9. Teva made an at-risk launch and began selling omeprazole in September 2004. ECF No. 131, ¶ 130; SOUF ¶ 9.

On May 31, 2007, the district court found that two of AstraZeneca's patents were valid and infringed by the omeprazole product manufactured by Impax and marketed by Teva. *In re Omeprazole Patent Litig.*, 490 F. Supp. 2d 381, 536 (S.D.N.Y. 2007); SOUF ¶ 12. The Federal Circuit affirmed the ruling of the district court in August 2008. *In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1382 (Fed. Cir. 2008); SOUF ¶ 13. The case then returned to the district court for damages proceedings. *Id.* On April 15, 2009, in response to a discovery motion filed by Teva, AstraZeneca conceded that it did not have a "lost profits" claim against Teva and therefore would be seeking reasonable royalty damages from Teva. Dec. 10, 2013 Declaration of Laurence A. Schoen ("Schoen Decl.") Ex. 7 at Teva-ESO-113857-58; SOUF ¶ 14. According to Teva's financial records, Teva's net sales of omeprazole during the less than three year period of infringement totaled $41.07 million, while the gross margin profits (net sales minus cost of goods sold) shared by Teva and Impax totaled $25.5 million. Dec. 10, 2013 Declaration of Jamie Berlanska ("Berlanska Decl.") ¶¶ 2-3 & Ex. 1; Schoen Decl. Ex. 6; SOUF ¶ 16.

On January 6, 2010, Teva and AstraZeneca entered into the Prilosec settlement, pursuant to which Teva paid AstraZeneca $9 million to resolve the Prilosec litigation against both Teva and Impax. Schoen Decl. Ex. 2; SOUF ¶ 15. The $9 million Prilosec settlement amount equals 21.9% of Teva's omeprazole net sales and 35.3% of the gross margin profits shared by Teva and Impax on those sales. Berlanska Decl. ¶¶ 2-3 & Ex. 1; Schoen Decl. Ex. 6; SOUF ¶ 16. The Prilosec settlement was negotiated and reached at the same time as the Nexium settlement. Schoen Decl. Exs. 1-2; SOUF ¶ 17. Neither settlement, however, was contingent on the other nor contained any term providing for any payment from AstraZeneca to Teva. *Id.*

LEGAL STANDARD

At the Rule 12 stage, this Court ruled that allegations of *non-monetary* payments may sometimes be sufficient to satisfy *Actavis*' requirement of a "reverse payment," and found that plaintiffs had sufficiently alleged a reverse payment to survive a motion to dismiss. *See* Op. 43. Even assuming *arguendo* that a non-monetary reverse payment can in some circumstances satisfy *Actavis*, plaintiffs still must prove a ***payment***. Moreover, to survive a Rule 56 motion, plaintiffs need more than assumptions about what they may be able to prove based on the allegations in their complaints. *Berkowitz v. Berkowitz*, Case No. 11-10483-DJC, 2013 WL 5328285, at *1 (D. Mass. Sept. 20, 2013) ("[T]he non-moving party may not rest on the allegations or denials in his pleadings,…but must come forward with specific admissible facts showing that there is a genuine issue for trial.") (citations omitted).

"Summary judgment is warranted if, after reviewing the facts in the light most favorable to the non-moving party, no genuine issues of material fact remain, and the moving party is entitled to judgment as a matter of law." *Celotex Corp.*, 477 U.S. at 325, 106 S Ct. 2548. "The movant has the initial burden of production, which it can meet either by offering evidence to disprove an element of the plaintiff's case or by demonstrating an 'absence of evidence to support the non-moving party's case.'" *Id*. "Once the movant has met its burden, the non-moving party must go beyond the pleadings, and by [its] own affidavits, or by the depositions, answers to interrogatories, and admissions on file, designate specific facts showing there is a material issue for trial." *CSX Transp., Inc. v. Recovery Express, Inc.*, 415 F. Supp. 2d 6, 9 (D. Mass. 2006) (Young, J.) (internal quotations and citation omitted). "'The moving party is entitled to judgment as a matter of law if the nonmoving party does not adduce enough evidence to permit a reasonable trier of fact to find for the nonmoving party on any element essential to its claim.' *Milton v. Van Dorn Co.*, 961 F.2d 965, 969 (1st Cir. 1992). The party bearing the

burden of proof must produce more than a 'scintilla of evidence on each element essential to its claim, thus affording the jury a nonconjectural basis for concluding that the fact to be inferred [is] more probable than its nonexistence.' *Id*. (quoting *Malave-Felix v. Volvo Car Corp*., 946 F. 2d. 967, 970-71 (1st Cir. 1991))." *Ilog, Inc. v. Bell Logic*, 181 F. Supp. 2d 3, 5 (D. Mass. 2002) (Young, J.).

ARGUMENT

I. THE UNDISPUTED RECORD NOW SHOWS PLAINTIFFS CANNOT PROVE THAT TEVA RECEIVED ANY REVERSE PAYMENT UNDER *ACTAVIS*.

Teva is entitled to summary judgment, as a matter of law, because plaintiffs have failed to meet their burden of demonstrating a payment to Teva. As defined by the Supreme Court in *Actavis*, a reverse payment agreement necessitates a payment ***from*** the brand ***to*** the generic:

> Company A sues Company B for patent infringement. The two companies settle under terms that require (1) Company B, the claimed infringer, not to produce the patented product until the patent's term expires, and (2) Company A, the patentee, to pay B many millions of dollars. Because the settlement ***requires the patentee to pay the alleged infringer***, rather than the other way around, this kind of settlement agreement is often called a 'reverse payment' settlement agreement.

133 S. Ct. at 2227 (emphasis added unless otherwise noted).

The Supreme Court's concern centered around so-called "reverse payment settlements" where "a party with no claim for damages…walks away with money simply so it will stay away from the patentee's market." *Id*. at 2233. In short, the Supreme Court's analysis commences with (and requires) the presence of a payment from the brand to the generic. While this Court held at the 12(b)(6) stage that a reverse payment need not be a "monetary" payment, it *still must be a payment*. Op. 42; *Actavis* 133 S. Ct. at 2227. Litigating parties do not "risk[] antitrust liability" if they settle their lawsuit "in other ways, for example, by allowing the generic manufacturer to enter the patentee's market prior to the patent's expiration, without the patentee paying the challenger to stay out prior to that point." *Actavis*, 133 S. Ct. at 2237.

Here, Teva's Nexium and Prilosec settlements do not satisfy *Actavis'* threshold criterion: neither provides for any payment whatsoever from AstraZeneca to Teva. To the contrary, in the Nexium settlement, Teva was permitted to enter the Nexium market prior to the expiration of AstraZeneca's patents and received no payment. In the Prilosec settlement, Teva (the generic company) paid $9 million ***to*** AstraZeneca (the branded patent holder). That is no reverse payment. *See id.* at 2227. Instead, plaintiffs ***allege*** that "payment [to Teva] came in the form of AstraZeneca's forgiveness of Teva from patent infringement liability" for Prilosec, ECF No. 131 ¶ 129, and that AstraZeneca "paid" Teva by discharging this "contingent liability," *id.* ¶ 130. *See* ECF No. 114 ¶ 101; ECF No. 515 ¶ 115; ECF No. 516 ¶ 114; ECF No. 517 ¶ 113. As an initial matter, the Nexium settlement agreement contains no promise by AstraZeneca to forgive Teva of any contingent liability. SOUF ¶ 6. To the contrary, each agreement contains clauses expressly stating that it recites the "entire agreement" and that "no other rights, agreements, or covenants are granted or implied by" the settlement agreement. *Id.* ¶¶ 6, 15.

In any event, plaintiffs' argument that compromising a damages claim at a "discount" below the alleged "value" of that claim constitutes an actionable "implicit net payment" from the patent holder to the infringer was squarely rejected by the Supreme Court in *Actavis*:

> [W]hen Company A sues Company B for patent infringement and demands, say, $100 million in damages, it is not uncommon for B (the defendant) to pay A (the plaintiff) some amount less than the full demand as part of the settlement -- $40 million for example. See Schlidkraudt, Patent-Splitting Settlements and the Reverse Payment Fallacy, 71 Antitrust L.J. 1033, 1046 (2004) (suggesting that this hypothetical settlement includes 'an implicit net payment' from A to B of $60 million, *i.e.*, the amount of the settlement discount)…. Insofar as the dissent urges that settlements taking these commonplace forms have not been thought for that reason alone subject to antitrust liability, we agree, and do not intend to alter that understanding.

133 S. Ct. at 2233.

Plaintiffs' argument concerning the Prilosec settlement boils down to the contention that AstraZeneca should have demanded more money. This argument fails as a matter of law. The Supreme Court did not hold, or suggest, that compromising a damages claim could constitute an effective "reverse payment" under any circumstances, particularly where that compromise involves the accused infringing generic paying the patent holder. To the contrary, the Court expressly held that settlements of such a nature are "***commonplace***" and are ***not*** subject to antitrust liability. *Actavis*, 133 S. Ct. at 2233; *id.* ("[t]raditional[ly]…a party with a claim (or counterclaim) for damages receives a sum ***equal to or less*** than the value of its claim.").

Nor did *Actavis* authorize second-guessing of compromised damages claims or hindsight valuation analyses of what the plaintiff ***might*** have recovered absent settlement of the type that plaintiffs offer here. The very example the Court provided involved a steep discount from the claimed damages — $100 million demand, and $40 million settlement — and the Court in ***no way*** suggested that the merits of the underlying case would have to be assessed to determine whether the plaintiff accepted too little. Such an inquiry would require a court to examine not just the merits of the litigation, but the parties' perceptions as to their chances of success, their level of risk aversion, business considerations, etc. Had the Supreme Court intended to permit such an inquiry, there is no question it would have made that intention clear.

The Supreme Court has recognized that "[i]t is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case." *Whitmore v. Arkansas*, 495 U.S. 149, 159-60 (1990); *see Christiansburg Garment Co. v. EEOC*, 434 U.S. 412, 421-22 (1978); *In re Cipro*, 261 F. Supp. 2d 188, 200 (E.D.N.Y. 2003). To allow antitrust plaintiffs to second-guess patent damage settlements would turn every such settlement into a potential reverse payment. The potential for chilling routine settlements is obvious. *See, e.g., In*

re Cipro, 261 F. Supp. 2d at 251-52 (parties typically settle for less than the full value of their claims; a rule transforming such settlements into antitrust violations "would discourage any rational party from settling a patent case."); *cf. Hillis v. Equifax Consumer Servs. Inc.*, Nos. 104-CV-3400-TCB, 107-CV-314-TCB, 2007 WL 1953464, at *10 (N.D. Ga. June 12, 2007) ("[S]ettlements, by their nature, do not yield one hundred percent recovery for plaintiffs."). This is precisely why the *Actavis* Court went out of its way to say that such "***commonplace***" damage settlements should not be second-guessed.

The evidence is now clear that the Prilosec settlement falls precisely within this traditional safe harbor. Plaintiffs merely contend that AstraZeneca ***could*** have recovered more had they proceeded with a damages trial. Because the *Actavis* Court ruled that settling a damages claim for less than its full alleged value does not give rise to antitrust liability, summary judgment must enter for Teva.

II. PLAINTIFFS OFFER NO EVIDENCE THAT TEVA'S PRILOSEC SETTLEMENT WAS GROSSLY INADEQUATE OR SHAM.

Given that the Supreme Court has recognized that settling a patent infringement damages claim at a 60% "discount" is not actionable, *Actavis*, 133 S. Ct. at 2233, for such a settlement to conceivably amount to a reverse payment, it would need to be so far outside the range of reasonableness as to be a sham — something which plaintiffs do not even allege, much less come forward with evidence of, here. Put another way, unless the settlement is grossly inadequate (akin to "waste" under the Business Judgment Rule), it cannot be used as a proxy for a "reverse payment" under *Actavis*.[1] Antitrust liability does not turn on whether consumers after

[1] It is well-established that the Business Judgment Rule prohibits a court from assessing the merits of a company's business decisions. *Rathburn v. Autozone, Inc.*, 361 F.3d 62, 74 (1st Cir. 2004) (citing *Mesnick v. Gen. Elec. Co.*, 950 F.2d 816, 825 (1st Cir. 1991)). Accordingly, a plaintiff bringing a corporate waste claim must prove "that the exchange was so one sided that no business person of ordinary, sound judgment could conclude that the corporation has received adequate consideration." *See In re Walt Disney Co. Deriv. Litig.*, 906 A.2d 27, 74 (Del. 2006) (internal

the fact think the "right" amount for a settlement (or any transaction) should have been *x* versus *y*. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514, 536 (E.D.N.Y. 2005) ("if defendants were within their rights … in reaching the settlement they did, consumers have no right to second-guess whether some different agreement would have been more palatable"), *aff'd in part*, 544 F. 3d 1323 (Fed. Cir. 2008). Likewise, the law cannot be that a drug manufacturer risks potential liability anytime it settles two patent cases contemporaneously, when either settled alone would be lawful.

Plaintiffs here have not come forward with any evidence sufficient to prove the Prilosec settlement was a sham. To the contrary, the sole purported basis for their claims against Teva is the testimony of three proposed experts, each of whom opines only that the Prilosec settlement amount was less than the full value of AstraZeneca's claims, and therefore supposedly constituted "forgiveness" of a contingent liability. The only plaintiffs' expert who attempted to quantify this purported "forgiveness," Dr. Thomas McGuire, pegged it at $23 million. Aug. 23, 2013 Report of Richard G. Frank & Thomas G. McGuire (Schoen Decl. Ex. 3) ("McGuire Rep.") ¶ 193 (estimating amount at $24.4 million); Nov. 25, 2013 McGuire Dep. (Schoen Decl. Ex. 5) 278:12-14 (reducing figure to $23.4 million to correct for mathematical error). As set forth *infra*, the conclusory opinions of these experts are inadmissible, and therefore cannot be used to establish that the Prilosec settlement reflected any "discount" at all. But even assuming, purely for sake of argument, that such testimony were admissible, none of plaintiffs' experts opines that the $9 million Prilosec settlement was so far below the value of AstraZeneca's damages claims as to be grossly inadequate or amount to a "sham." Indeed, at his deposition, Dr. McGuire said

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quotations and citation omitted). A court applying *Actavis* and evaluating the objective reasonableness of a business transactions (*i.e.*, a reverse payment) should undertake a similar analysis.

he is not even comfortable calling the Prilosec settlement a "sweetheart deal" for Teva, and recanted the language in his report to that effect. McGuire Dep. 203:1-14.

Further, recent developments in patent infringement litigation between AstraZeneca and Apotex, another generic company found to have infringed AstraZeneca's Prilosec patents, conclusively establish that the Prilosec settlement between Teva and AstraZeneca is not so far outside the range of reasonableness as to constitute a sham. Apotex began selling omeprazole nine months prior to Teva, and was found to infringe AstraZeneca's patents in the same trial as Teva. SOUF ¶ 22. Apotex did not settle its claims, proceeded to trial, and ultimately was ordered to pay a royalty equal to 50% of its gross margin profits on its infringing omeprazole sales. *Id*.; Schoen Decl. Ex. 17. If Teva were ordered to pay a royalty based on the same type of calculation, it would yield *at most* a payment of $12.75 million.[2] After taking avoided litigation costs, the time value of money and other risks into account, no reasonable jury could find that the difference between the $9 million Prilosec settlement and the $12.75 million "value" of this claim constitutes a "discount," let alone a "discount" so far outside the range of reasonableness so as to be "grossly inadequate" or sham.

Without evidence that a settlement is a sham, courts should not second-guess the price at which litigants resolve a disputed damages claim, as to do so would have an undesirable chilling effect on such settlements and undermine the strong public policy in favor of such compromises. *See In re Cipro*, 261 F. Supp. 2d 252 (allowing an antitrust claim based on assertion that settlement was for less than full value "would discourage any rational party from settling a patent case"). Courts have long and uniformly recognized that "the American legal process encourages

[2] The gross margin profits shared by Teva and Impax on Teva's omeprazole sales totaled $25.5 million, Berlanska Decl. ¶¶ 2-3 & Ex. 1, so applying 50% to that figure would yield $12.75 million in royalty damages. If one were to focus only on the gross margin profits retained by Teva, then the $9 million settlement amount equals approximately 54% of those profits, as the district court in *Apotex* found. Schoen Decl. Ex. 17 at 77 & n.30.

the settlements of lawsuits when possible." *Id.* at 256*; see Bano v. Union Carbide Corp.*, 273 F.3d 120, 129 (2d Cir. 2001) ("[I]t is axiomatic that the law encourages the settlement of disputes."); *Williams v. First Nat'l Bank*, 216 U.S. 582, 595 (1910) ("[c]ompromises of disputed claims are favored by the courts"). Especially given the complex issues presented by patent litigation, "[s]ettlement is of particular value in patent litigation." *Aro Corp. v. Allied Witan Co.*, 531 F.2d 1368, 1372 (6th Cir. 1976); *see Flex-Foot, Inc. v. CRP, Inc.*, 238 F.3d 1362, 1370 (Fed. Cir. 2001); *Foster v. Hallco Mfg. Co.*, 947 F.2d 469, 477 (Fed. Cir. 1991). In the context of Hatch-Waxman patent litigation in particular, reducing the risks of litigation through settlement lowers the costs of bringing an ANDA patent challenge, making it more likely generic companies will invest the time and money into bringing such challenges. Without the ability to freely settle patent litigation, "the incentives to mount an ANDA IV challenge could be reduced." *In re Cipro*, 261 F. Supp. at 256. Settlement is a key tool for managing the expense and uncertainty of litigation. *See, e.g.*, D. Marie Provine, *Settlement Strategies for Federal District Judges* 1 (Fed. Judicial Ctr. 1986) ("Settlements are desirable, not just because trials are costly…but because settlements allow parties to 'manage their own disputes' and avoid the uncertainties and limitations of the winner-take-all imposed decisions that courts make in fully litigated cases."), *available at*, www.fjc.gov/public/pdf.nsf/lookup/sttlstrt.pdf/$file/sttlstrt.pdf.

Accordingly, courts should not second-guess business decisions made by officers charged with managing such disputes. As with the Business Judgment Rule, which protects management's decisions unless "no reasonable business person" would have made the decision, the court should not substitute its judgment regarding the "reasonableness" of a settlement payment. *See Pirelli Armstrong Tire Corp. v. Retiree Med. Benefits Trust*, 534 F.3d 779, 791 (D.C. Cir. 2008); *see Cottle v. Storer Comm'ns, Inc.*, 849 F.2d 570, 577 (11th Cir. 1988) (to

"overcome the business judgment rule" a price challenge "must be based on a ***gross inadequacy*** of price"). Nowhere do plaintiffs present evidence or even allege that the Prilosec settlement was grossly inadequate, so plaintiffs should not be permitted to "second-guess" it. *Storer*, 849 F.2d at 577.

III. EVEN UNDER THEIR FLAWED STANDARD, PLAINTIFFS HAVE NOT COME FORWARD WITH ANY ADMISSIBLE EVIDENCE SUFFICIENT TO PROVE AN "EFFECTIVE" REVERSE PAYMENT TO TEVA.

Even assuming, purely for sake of argument, that plaintiffs were correct that it is appropriate for this Court to scrutinize the settlement of a damages claim for patent infringement for "reasonableness," plaintiffs have not met their burden to come forward with any admissible evidence sufficient to prove that the $9 million paid by Teva in the Prilosec settlement is "unreasonable" in comparison to the amount that AstraZeneca stood to recover in the Prilosec litigation. That is, even under plaintiffs' construction of the appropriate legal standard, plaintiffs cannot meet their burden to prove an essential element of their claims.

In order to assess the "reasonableness" of the Prilosec settlement, it is first necessary to determine what AstraZeneca reasonably stood to recover from Teva in the Prilosec litigation. As plaintiffs' own expert concedes:

> At the time of Teva's launch [of generic omeprazole], five other generic manufacturers were selling omeprazole in the U.S. In calculating the amount that Teva would have reasonably owed AstraZeneca [absent the settlement] it is important to take the existence of other generic entrants into consideration. It is likely that, if Teva had not entered, buyers of Teva's generic product would have purchased from one of the other five generics and not from the brand [AstraZeneca]. As such, it is reasonable and certainly conservative to evaluate the Prilosec agreement based on a reasonable royalty.

McGuire Rep. ¶ 190; *see* SOUF ¶¶ 9, 19. Indeed, well prior to the settlement, AstraZeneca conceded it was not pursuing lost profits against Teva and was claiming reasonable royalty damages. Schoen Decl. Ex. 7 at Teva-ESO-113857-58; SOUF ¶ 14.

Because the damages phase of the Prilosec litigation was still in its early stages, expert testimony is the only way plaintiffs could possibly establish the amount of royalty damages that AstraZeneca reasonably stood to recover absent the settlement. *See* SOUF ¶¶ 18-20. Plaintiffs have designated three experts for this purpose (Dr. Thomas G. McGuire and Attorneys Shashank Upadhye and John R. Thomas), but as set forth in Teva's *Daubert* motion filed today, none of them utilized a reliable methodology, which satisfies the requirements of *Daubert* and Fed. R. Evid. 702, rendering their testimony inadmissible and insufficient to establish any genuine issue of material fact.

As this Court has recognized, reasonable royalty damages in a patent infringement case are measured by the fifteen *Georgia Pacific* factors first articulated by Judge Tenney. *Avco Corp. v. PPG Indus.*, 867 F. Supp. 84, 99 (D. Mass. 1994) (citing *Georgia Pacific Corp. v. United States Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), *modified* 446 F.2d 295 (2d Cir. 1971), *cert. denied*, 404 U.S. 870 (1971)); *see Uniloc USA v. Microsoft Corp.*, 632 F.3d 1292, 1317 (Fed. Cir. 2011). And yet, Dr. McGuire and Attorneys Upadhye and Thomas ***ignore*** entirely the *Georgia-Pacific* factors, making no mention of them at all in their respective expert reports. Accordingly, they have not employed anything close to the "same level of intellectual rigor that characterizes the practice of an expert in the relevant field," *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999), and do not satisfy the requirements of Rule 702.

The conclusory opinions of Attorneys Upadhye and Thomas are pure *ipse dixit*, and therefore are plainly inadmissible. *McGovern v. Brigham & Women's Hosp.*, 584 F. Supp. 2d 418, 426 (D. Mass. 2008). Attorney Upadhye baldly asserts that AstraZeneca's damages in the Prilosec Litigation "were likely in the tens of millions of dollars," but offers no explanation at all for how he arrived at that estimate, and does not make any reference at all to the governing

Georgia-Pacific factors. Aug. 23, 2013 Report of Shashank Upadhye (Schoen Decl. Ex. 8) ("Upadhye Rep.") ¶ 258. At his deposition, Attorney Upadhye admitted that he did not make any computations or perform any systematic analysis of any kind to reach this conclusion. Nov. 7, 2013 Upadhye Dep. (Schoen Decl. Ex. 10) 360:19-362:10.

Similarly, Professor Thomas baldly states that Teva "faced significant liability" from its infringing Prilosec sales, and that in the Prilosec Settlement, Teva agreed to pay a "far smaller amount," but offers no quantification of this purported difference or explanation of how he "arrived" at this conclusion. Aug. 23, 2013 Expert Report of John R. Thomas (Schoen Decl. Ex. 11) ("Thomas Rep.") ¶ 70. Professor Thomas admitted that: (i) AstraZeneca was seeking reasonable royalty damages in the Prilosec case; (ii) he did not undertake any analysis to calculate the reasonable royalty damages that AstraZeneca stood to recover from Teva; and (iii) the quantification of reasonable royalty damages is a matter he would leave "… more to economists" and is "not straight up [his] area of expertise." Oct. 30, 2013 Thomas Dep. (Schoen Decl. Ex. 12) 209:16-212:17. In short, there is no methodology at all, or foundation of any kind, supporting these opinions of Attorneys Upadhye and Thomas.[3] SOUF ¶ 20.

Dr. McGuire is the sole expert proffered by plaintiffs who purports to quantify the "value" of AstraZeneca's Prilosec claims, but his opinion is not supported by a reliable methodology, and therefore must be excluded as well. The entirety of Dr. McGuire's purported quantification of the reasonable royalty "owed" by Teva is contained in Paragraphs 191 to 193 of his original report. In Paragraph 191, Dr. McGuire "estimates" Teva's total omeprazole profits,

[3] In his rebuttal report, Attorney Upadhye offers one supposed new "ground" for his opinion: given that AstraZeneca sought hundreds of millions in damages from Andrx — the first generic company to manufacture omeprazole but one that never sold it on the market — it "strains credulity" to "suggest that Teva's entire liability for its ***actual*** launch of generic omeprazole would be $9 million or less." Oct. 25, 2013 Reply Report of Shashank Upadhye (Schoen Decl. Ex. 9) ¶ 14. But Attorney Upadhye fails to mention that even though AstraZeneca ***sought*** such damages from Andrx, AstraZeneca did not prevail on that damages claim, and in the trial court's final judgment, recovered ***zero damages***. *Astra Aktiebolag et al v. Andrx Pharms.*, Civ. A. No. 99-cv-09887-DLC, Consent Order and Final Judgment (ECF No. 259) (S.D.N.Y. Sept. 30, 2013) (Schoen Decl. Ex. 15).

an exercise that was necessary only because plaintiffs failed to provide him with the Teva financial records showing the exact amount of Teva's omeprazole net sales and profits. Based on his *extrapolation*, Dr. McGuire "assumes" that Teva earned net profits on omeprazole of $43.0 million, McGuire Rep. ¶ 191, a figure which substantially exceeds the actual gross margin profits of $25.5 million shared by Teva and Impax. Berlanska Decl. ¶¶ 2-3; SOUF ¶ 16. Dr. McGuire, however, admitted he has no basis to disagree with the profit figures in Teva's records. McGuire Dep. 284:13-285:1; SOUF ¶ 16. Dr. McGuire next assumes that "[i]f AstraZeneca had claimed an 80% royalty fee, which it did in multiple distribution agreements with Ranbaxy, Teva/Impax would have owed AstraZeneca $34.4 million ($43.0 million*80%)." McGuire Rep. ¶ 192. Dr. McGuire identifies those two agreements as the Distribution Agreements for Prilosec and Plendil, pursuant to which AstraZeneca gave Ranbaxy the right to distribute authorized generics of those drugs. McGuire Dep. 200:16-201:12. Dr. McGuire then takes his $34.4 million "royalty" that he says AstraZeneca could have "collected," subtracts the $9 million settlement amount and $2 to $3 million of avoided litigation costs, and arrives at an effective payment to Teva of "at least $24.4 million." McGuire Rep. ¶ 193. Dr. McGuire later reduced this figure to $23.4 million to account for an arithmetic error. McGuire Dep. 276:19-278:14.

Dr. McGuire ***admits*** that his calculation does ***not*** apply the legally mandated methodology for estimating reasonable royalty damages in a patent case. SOUF ¶ 20. He testified that: (i) the *Georgia-Pacific* factors are the "accepted methodology" for measuring reasonable royalty damages, McGuire Dep. 279:17-280:11; (ii) he possesses the requisite economic training to apply such factors, *id.* at 202:4-19; (iii) he nonetheless did not even attempt to perform any analysis of the *Georgia-Pacific* factors, *id.* at 202:20-22, 280:4-281:2; and (iv) he has no basis to disagree with the analysis of the *Georgia-Pacific* factors performed by Teva's

expert, Philip Green, *id.* at 280:14-281:2, who concluded that the $9 million Prilosec settlement amount "is consistent with, and may well exceed, the range of amounts that AstraZeneca reasonably stood to recover absent a settlement." Sept. 30, 2013 Expert Report of Philip Green (Schoen Decl. Ex 13) ("Green Rep.") 4.

Moreover, even though Dr. McGuire's affirmative expert report states that a "reasonable royalty" analysis is the relevant inquiry, McGuire Rep. ¶ 190, and describes his "calculation" in Paragraph 192 of his report as a "royalty fee," at his deposition, Dr. McGuire ***admitted*** that his "calculation" actually does ***not*** actually approximate a reasonable royalty, McGuire Dep. 195:3-12. "[P]robably if I were rewriting it now, I would get rid of the word 'royalty,' which I think is a little misleading there." *Id.* at 279:5-8. Dr. McGuire now says that, instead of a "royalty" analysis, his "calculation" is designed to estimate the profit sharing "fee" that AstraZeneca supposedly could have claimed if it was negotiating with Teva for a distribution agreement for an ***authorized generic***. *Id*. at 196:22-198:20. This analysis does not "fit" the facts of the case, and will not assist the jury, *see McGovern,* 584 F. Supp. 2d at 423, as: (i) the Prilosec litigation between AstraZeneca and Teva undisputedly had nothing to do with a distribution agreement for an authorized generic, but rather concerned Teva's infringing sales of non-authorized generic omeprazole manufactured by Impax, McGuire Dep. 196:10-18; (ii) Dr. McGuire admits that he is not aware "of any patent infringement case where damages were measured by reference to the royalty rate in distribution agreements for authorized generics," *id.* at 293:18-22; and (iii) the economic considerations that go into negotiating the profit sharing rate for an authorized generic distribution agreement are very different than the economic considerations that go into the negotiation of a royalty rate for a patent license, *id.* at 196:10-18, 292:16-293:17. *See* Green Rep. 27-28 (explaining differences in economics of authorized generic distribution agreements).

As this Court has noted, an "authorized generic is essentially a brand-name drug produced by a brand manufacturer but marketed under a generic label," so the generic distributor of such a drug incurs no manufacturing costs. Op. 11. Here, in contrast, Teva separately paid Impax to manufacture the generic omeprazole that Teva marketed. Further, and again as this Court has recognized, one of the primary purposes of an authorized generic distribution agreement is to take advantage of the more limited generic competition that occurs during the Hatch-Waxman 180-day exclusivity period for the first ANDA filer, during which generic profits are much higher than they are after that period ends. *Id.* at 11-12. Because Teva did not sell an authorized generic version of Prilosec and launched its generic product nearly two years after the first generic entrant, Teva had no opportunity to take advantage of the 180-day exclusivity period from which an authorized generic distributor usually benefits. Green Rep. 27-29.

Because neither Dr. McGuire nor Attorneys Upadhye or Thomas applied a reliable methodology consistent with the rigor expected of an expert in the field, and ignored the legally operative *Georgia-Pacific* standard for assessing royalty damages, their conclusory opinions purporting to estimate Teva's exposure in the Prilosec litigation are inadmissible. As plaintiffs have not come forward with any other purported evidence sufficient to show the Prilosec settlement was "unreasonable" or reflected a "discount" to Teva, plaintiffs cannot prove an essential element of their claims even under their own (flawed) construction of the appropriate legal standard. Accordingly, Teva is entitled to summary judgment.

IV. TEVA IS ALTERNATIVELY ENTITLED TO SUMMARY JUDGMENT BECAUSE ANY REVERSE PAYMENT IS NOT LARGE AND UNEXPLAINED.

Even if there was any triable issue as to the existence of a "reverse payment" to Teva (which there plainly is not), plaintiffs also cannot prove that any such payment was "large" and "unexplained" as required to trigger antitrust scrutiny under *Actavis.* That is, even accepting the

inadmissible expert testimony proffered by plaintiffs that the Prilosec settlement reflects an effective $23 million "discount" to Teva, no reasonable jury could find this constitutes a "large" reverse payment intended to compensate Teva for "staying out" of the Nexium market until May 2014, given that plaintiffs themselves allege that the Nexium market opportunity exceeded ***$3 billion annually***. SOUF ¶ 2. According to *Actavis*, the "size of the unexplained reverse payment can provide a workable surrogate for the patent's weakness." *Actavis*, 133 S. Ct. at 2236-37. It defies all logic to suggest that Teva believed AstraZeneca's Nexium patents were weak, but "gave up" the opportunity for billions of dollars in ***annual*** Nexium revenues in exchange for an alleged $23 million in one-time "savings" in the Prilosec Settlement.

Nor can plaintiffs meet their burden to prove that any such "discount" to Teva was "unjustified," given the millions of dollars in litigation costs and diversion of employee time that AstraZeneca would have incurred in the Nexium and Prilosec litigation, but was able to avoid by virtue of the settlements. Once these costs are taken in account, it is even more clear the "payment" plaintiffs allege is neither large nor unexplained. *See Actavis*, 133 S.Ct. at 2235, 2236 (acknowledging legitimacy of "litigation expenses saved through the settlement" and noting that "avoided litigation costs" are acceptable "traditional settlement considerations").

CONCLUSION

For the foregoing reasons, Teva respectfully requests that the Court enter summary judgment in favor of Teva with respect to all of plaintiffs' claims against it.

Dated: December 10, 2013

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on the 10th day of December 2013, I filed and served the foregoing via the Court's CM/ECF system, which will serve notification of such filing by email to all counsel of record.

/s/Laurence A. Schoen
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